510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. **Submitter:** L&K BIOMED Co., Ltd.
   #1104, Ace High-end Tower 3 cha, 371-50, Gasan-Dong, Geumcheon-gu, Seoul 153-803 Republic of Korea

   Contact Person: Hee Kyeong Joo
   Phone. 82-2-2624-1475
   FAX .82-2-2624-1477
   E-mail: hkjoo83@gmail.com

   Date Prepared January 6, 2012

2. **Device Identification**

Trade Name	VENUS Lumbar Intervertebral body Fusion Cage System
Common/Usual Name	Intervertebral Fusion Device
Regulation Name	Intervertebral body fusion device (21 CFR 888.3080)
Regulatory Class	Class II
Product Code	MAX

3. **Description of the Device**

The VENUS Lumbar Intervertebral body Fusion Cage System is intend to help provide support in the intervertebral body space during fusion of vertebral bodies in the lumbar spine. This system is intended to be used with supplemental fixation. The VENUS Lumbar Intervertebral body Fusion Cage System consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The Implants are made of PEEK-OPTIMA® LTI body with the titanium marker pins made of Titanium alloy (Ti-6Al-4V ELI). The purpose of this submission is to add a new Lumbar Interbody device: VENUS DLIF Cages and to expand the size of the devices.

4. **Indications for Use**

VENUS Lumbar Intervertebral body Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. VENUS Lumbar Intervertebral body Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

5. **Non-clinical Testing**

The proposed line extension for the VENUS Lumbar Intervertebral body Fusion Cage System does not constitute a new worst case for the intended use and is substantially equivalent to the predicate device (K110783).

6. **Summary of technology characteristics**

The VENUS Lumbar Intervertebral body Fusion Cage System shares technological characteristics similar to the predicate devices. These characteristics include similar design, the same materials and the same intended use.

7. **Predicate or legally marketed devices which are substantially equivalent**

The design feature and indications for use for the subject VENUS Lumbar Intervertebral body Fusion Cage System is substantially equivalent to the following predicates:

- **L&K BIOMED**: VENUS Lumbar Intervertebral Body Fusion Cage System(K110783)
- **GS Medical**: Any Plus PEEK Cage (K100516)
- **STRYKER SPINE** :AVS PEEK Spacer System (K083661,K090816,K093704)
- **Solco Biomedical** : 4CIS PEEK PLIF Cage System (K092162)
- **Spine Art** : JULIET OL , DYNAMIK Intervertebral body fusion device (K081888, K101720)
- **Medtronic Sofamor Danek**: CLYDESDALE Spinal System (K100175,K112405,K113528)

8. **Conclusion**

The VENUS Lumbar Intervertebral body Fusion Cage System is substantially equivalent to the device referenced above and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

L&K BIOMED Company, Limited
% Hee Kyeong Joo
Manager
#1104, Ace High-end Tower 3 cha, 371-50, Gasan-Dong
Geumcheon-gu, Seoul 153-803
Republic of Korea

APR 19 2012

Re: K120063
Trade/Device Name: VENUS Lumbar Intervertebral body Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: March 28, 2012
Received: March 30, 2012

Dear Hee Kyeong Joo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K120063

Device Name : VENUS Lumbar Intervertebral body Fusion Cage System

Indications for Use :

VENUS Lumbar Intervertebral body Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. VENUS Lumbar Intervertebral body Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use ____√___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120063